No. 96-1451

Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1996

COLLAGEN CORPORATION,

Cross-Petitioner,

vs.

IRENE GREEN and MARTIN GREEN,

Cross-Respondents.

On Conditional Cross-Petition for Writ of Certiorari to the Supreme Court of Pennsylvania

BRIEF OF IRENE AND MARTIN GREEN IN RESPONSE TO CONDITIONAL CROSS-PETITION

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts state tort law claims against a manufacturer and treating physician to recover for injuries caused by a PMA-approved Class III medical device.

STATEMENT OF THE CASE

Cross-respondents Irene Green and Martin Green respectfully request that this Court deny the conditional cross-petition for writ of certiorari filed by cross-petitioner Collagen Corporation, which seeks partial review of the Pennsylvania Supreme Court's opinion in this case. The Pennsylvania Supreme Court's opinion is reported at 685 A.2d 110 (1996).

In its conditional cross-petition, cross-petitioner Collagen Corporation specifically relies on the facts and proceedings as reported in its brief in response to the petition filed by Irene and Martin Green in No. 96-1340. The facts set out by cross-petitioner Collagen Corporation in its response ("Coll. Resp.") are incorrect, misleading and/or incomplete in the following respects.

1. Any assertion by Collagen Corporation that its Class III device Zyderm was approved under the FDA's regulations appearing at 21 C.F.R. § 814.20, *et seq.*, is incorrect. The PMA for Zyderm was approved in 1981 (Coll. Resp. 4). C.F.R. regulations for pre-market applications were not promulgated by the FDA until 1986, five years after approval of the Zyderm PMA.

2. Cross-petitioner Collagen Corporation's assertion that it cannot modify Zyderm's packaging or warnings without prior FDA approval is false. Cross-petitioner only *partially* cited the FDA's "conditions of approval" for Zyderm, stating that cross-petitioner cannot make any packaging or labeling changes without FDA approval. (Coll. Resp. 4). In truth, those portions of the conditions of approval *omitted* by cross-petitioner in its Brief unequivocally allow cross-petitioner to make packaging and labeling warning modifications *without* prior FDA approval where such changes would enhance safety and effectiveness.

Collagen Corporation's hands were not tied in the event it wanted to warn consumers and physicians of autoimmune risks and injuries regarding Zyderm.

3. The FDA had *not* in 1991 "reviewed Zyderm's record and reconfirmed in its initial finding of safety and effectiveness," as alleged by cross-petitioner (Coll. Resp. 4; Cross-Pet. 3). Rather, in response to a congressional investigation involving Collagen Corporation, the FDA re-reviewed the *original* 1980 PMA materials submitted by cross-petitioner for Zyderm, and determined that under 1980 standards, the PMA had been properly approved. Such a finding does not in any way act to rehabilitate what Collagen Corporation has done since, nor absolve Collagen of any fraud claims.

REASONS WHY THE CONDITIONAL CROSS-PETITION SHOULD BE DENIED

SECTION 360k(a) SHOULD NOT INSULATE DEVICE MANUFACTURERS FROM CLAIMS BASED IN THE FILING AND PURSUING OF FRAUDULENT PMAs FOR CLASS III MEDICAL DEVICES.

As the sole basis for its conditional cross-petition, Collagen Corporation argues that, above all, Section 360k(a) of the MDA should insulate it and other device manufacturers from fraud in the submission of PMAs. Stated differently, Collagen Corporation asks this Court to rule that a Class III device manufacturer should not be liable to persons injured by the device, where the device has been allowed on the market through the manufacturer's fraud on the FDA.

In fashioning this argument, Collagen admits that implicit in the MDA regulations is the requirement that device manufacturers not perpetrate fraud in PMA device submissions.

Collagen further admits that *Lohr* clearly holds that § 360k(a) allows state law claims which allege that a device has been manufactured or distributed in violation of FDA regulations. Despite this clarity of application, Collagen argues that fraud claims should nonetheless be preempted, as to allow fraud claims to proceed against it would somehow bring crashing down the entire FDA regulatory system.

Primarily, cross-petitioner Collagen Corporation contends that fraud claims would "impair the integrity of the federal regulatory scheme" (Cross-pet. 5), specifically by allowing a trial court to find that had the FDA known the "true" facts, it would not have granted marketing approval, or may have imposed different conditions of approval. This, states Collagen, impermissibly allows the trial court to substitute its finding for that of the FDA and hold that the device is not safe or effective.

This analogy, however, does not establish a "special" set of circumstances applicable only to fraud claims. By substituting *Lohr's* allowance of claims for improper manufacturing and distribution, *any* claim grounded on violation of FDA regulations, whether based in fraud or not, would be allowed under *Lohr*.

Moreover, Collagen's argument misses its mark — the question of fraud (as with that of violation of FDA requirements) focuses not on an invasive analysis of the FDA's actions, but on an inquiry into the *manufacturer's* actions under the circumstances. Cross-respondents' allegations that cross-petitioner Collagen Corporation acted fraudulently regarding its Zyderm device would not allow trial courts to substitute "their own views concerning whether and how a medical device is to be manufactured and marketed" (Cross-pet. 7). Rather, a finding of fraud is a finding of fraud; it does not undo the FDA's decisions, and does not create substitute administrative proceedings. It would not, contrary to Collagen's claim,

"requir[e] a court, applying state law, to perform the same functions initially entrusted to the FDA" (Cross-pet. 6).

Indeed, if anything could bring the FDA regulatory scheme crashing down and destroy the integrity of the entire process, it would be the past, present and future continued use of fraud by device manufacturers such as Collagen Corporation in the submission of medical device PMAs. The PMA scheme *relies* on honesty and complete disclosure by device manufacturers, as the FDA itself does not "second guess" the integrity of the submitted data. By allowing injured parties to pursue fraud claims, the MDA and FDA scheme would not be destroyed, but to the contrary (borrowing from Collagen Corporation's own language),

> such a process, if conducted with a proper understanding of the actual federal requirements, could serve to support and reinforce FDA's informed judgment concerning how the particular medical device should be manufactured and distributed.

(Cross-pet. 5).

In making this statement above (*Id.*), Collagen Corporation concedes that certain state tort laws could enhance the FDA administrative procedures regarding medical devices. If anything, fraud-based claims would greatly enhance FDA's procedures regarding medical devices — fraudulent submissions brought to light through litigation could be utilized by the FDA for its own administrative purposes. Collagen's specious protestations notwithstanding, there is no excuse, no justification, for allowing a device manufacturer to hide behind fraud to the detriment of consumers and the public at large.

This Court's ruling in *Lohr v. Medtronic* controls this issue. Fraud-based claims, in raising violations of the regulation requiring honesty and prohibition against deceit and falsification implicit within the MDA, would seek enforcement of the MDA regulations, and are expressly allowed by *Lohr.*

CONCLUSION

If the petition for a writ of certiorari is granted in No. 96-1340, *Green v. Collagen Corporation, et al.*, Collagen Corporation's conditional cross-petition should be denied.

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